

Appl. No. 10/675,669
Amdt. Dated 01/28/2007
Reply to Office Action of 10/27/2006

REMARKS / ARGUMENTS

For the convenience of the Examiner and clarity of purpose, Applicant has reprinted the substance of the Office Action in *10-point bolded and italicized font*. Applicant's arguments immediately follow in regular font.

3. The disclosure is objected to because of the following informalities: On page 1 in line 12, the date listed for Application No. 60/319,358, June 26, 2003, is incorrect. According to the IFW for said Application the correct date is June 26, 2002. Appropriate correction is required.

The Office is correct and paragraph [0001] has been amended accordingly.

5. Claims 15-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 15 and 24, "a time continuous signal" is inferentially included and it cannot be determined if the time continuous signal is being positively recited or functionally recited. It is also unclear what element is providing this signal and what it is related to. To positively claim the time continuous signal, it is suggested to first positively recite the time continuous signal. Otherwise, functional language such as "for" or "adapted to be" should be used.

Applicant has amended independent claims 15 and 24 to make plain that the pump generates the "time continuous signal" and that the processor is adapted to receive this signal.

Claims 16 and 17 recite the limitation "the sampled time continuous signal". There is insufficient antecedent basis for this limitation in the claims.

Claims 16 and 17 have been amended by removing the word "sampled."

In claim 18, the phrase "the signal to noise ratio" is vague. It is unclear which signal is being discussed and what element provides the noise signal.

Claim 18 has been amended to make plain that it is the signal to noise ratio of the “transformed time continuous signal.”

In claim 19, the phrase "the signal to noise plus distortion ratio" is vague. It is unclear which signal is being discussed and what element provides the noise plus distortion signal.

Claim 19 has been amended to make plain that it is the signal to noise ratio plus distortion ratio of the “transformed time continuous signal.”

Claim 23 recites the limitation "the sampling rate". There is insufficient antecedent basis for both occurrences of this limitation in the claim. Additionally, "a reference clock is inferentially included and it cannot be determined if the reference clock is being positively recited or functionally recited.

Claim 23 has been amended to positively recite that the analog to digital converter has a “sampling rate.”

Claim 28 recites the limitation "sampled data points". There is insufficient antecedent basis for this limitation in the claim.

Claim 28 has been amended to remove the word “sampled.”

In claim 29, it is unclear what the "3800 data points" represent as they appear to conflict with the 200 data points of claim 28.

Applicant submits that there is no conflict between claims 28 and 29. Claim 28, as amended, requires that the digital representation of the time continuous signal comprises less than about 200 data points. Claim 29 is directed to the processor and requires that it be programmed to zero pad at least about 3800 data points. There is no conflict. Claim 29 has not been amended in response to this objection.

7. *Claims 15-17 and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Antaki et al., U.S. Patent 5,888,242.*

8. *Antaki et al. disclose a blood pump control system (e.g. Fig. 1, element 10) comprising a processor receiving a time continuous signal from a blood pump system (e.g. elements 21 and 20; Figs. 3-6; column 1, lines 51-54; column 4, lines 33-34); a processor being programmed to transform a time continuous signal to a frequency domain (e.g. column 6, lines 31-37), and control a blood pump and detect excess suction in response to a time continuous signal in a frequency domain (column 6, line 25 where imminent ventricular collapse is ventricular suction as described in column 2, lines 14-15 and column 4, lines 31-32); a processor is further programmed to determine parametric data based on a sampled time continuous signal in a frequency domain (e.g. column 2, lines 34-38; column 4, lines 65-column 5, lines 1-2; column 5, lines 17-25; column 6, lines 48-52).*

Applicant respectfully traverses this rejection. Applicant understands Antaki to disclose detecting ventricular collapse by monitoring increasing **amplitude** of the second harmonic component of the motor current waveform as pump speed increases. Specifically, Antaki discloses:

Finally, in a third embodiment of the invention, it has been found that the second harmonic of the current fluctuation during a heartbeat cycle increases substantially shortly before ventricular collapse occurs. Thus, a spectral analysis representation of the time-current wave form during the heartbeat cycle can be continuously computed, and a speed reduction signal can be generated **when the second harmonic term of the series exceeds a predetermined threshold.**

Antaki at Col. 2, lines 31 – 38 (emphasis added).

In the third embodiment of the invention (FIG. 6), advantage is taken of the empirically discovered fact that the second harmonic component of the motor current waveform over a heartbeat cycle **rises substantially** as the pump speed approaches the ventricular collapse danger point. Consequently, another way of detecting imminent collapse is to compute a spectral analysis of the motor current I with the heartbeat frequency f as the fundamental frequency, and to trigger the imminent collapse flag when the **second harmonic coefficient A_2 exceeds a predetermined value A_{MAX} .**

Antaki at Col. 5, lines 14 – 19 (emphasis added).

Antaki has absolutely no disclosure or recognition of using **distortion** in the spectral

analysis of the motor current waveform (or any other frequency-transformed pump-based time continuous signal) for determining when ventricular collapse is likely. Indeed, the word “*distortion*” cannot be found in Ataki.

Applicant has chosen to amend independent claim 15 to require that “excess suction” is detected from distortion in the transformed signal. Support for this amendment may be found at page 22, line 19 through page 23, line 7, and continuing paragraphs.

Insofar as Antaki has no disclosure or appreciation of the invention of amended claim 15, independent claim 15 and dependent claims 16, 17 and 20 – 22 are patentable over Antaki. Reconsideration and withdrawal of this rejection is respectfully requested.

10. Claims 18, 19, and 23-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Antaki et al., U.S. Patent 5,888,242.

For at least the reasons set forth above with respect to claim 15, dependent claims 18, 19 and 23 are patentable over Antaki. Reconsideration and withdrawal of these rejections are respectfully requested. See Applicant’s arguments below for claims 24 – 29.

11. Regarding claim 24, Antaki et al. disclose a blood pump including a motor (e.g. element 14) having a rotor (e.g. column 1, lines 52-53 and 59-61); a motor controller coupled to a motor (column 1, lines 61-64; column 3, lines 9-12); a processor having inputs coupled to a motor controller for receiving a time continuous signal from a pump (e.g. elements 21 and 20; Figs. 3-6; column 1, lines 51-54; column 4, lines 33-34); a processor being programmed to transform a time continuous signal to the frequency domain, and control a pump and detect excess suction in response to a time continuous signal in the frequency domain (column 6, line 25 where imminent ventricular collapse is ventricular suction as described in column 2, lines 14- 15 and column 4, lines 31-32). Antaki et al. do not disclose a stator and a stator including a plurality of stator windings. However, it is well known in the art for a motor to have a stator that includes a plurality of stator windings to enhance and diversify a

motor's function to ensure optimal system performance in which the motor is used. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Antaki et al. to include a stator and a stator including a plurality of stator windings to enhance and diversify a motor's function to ensure optimal system performance in which the motor is used.

Without agreeing with the Office's characterizations of Antaki or with the application of Antaki to claim 24, Applicant has chosen to amend claim 24 to require that that "excess suction" is detected from distortion in the transformed signal. As discussed with respect to amended claim 15, Antaki has no recognition of or appreciation for this invention and, therefore, claim 24 is patentable over Antaki. Reconsideration and withdrawal of this rejection is respectfully requested.

12. Antaki et al. disclose the essential features of the claimed invention as described above except for a processor is programmed to calculate a signal to noise ratio (claim 18), a signal to noise plus distortion ratio (claim 17) and to zero pad a received time continuous signal (claim 27) and to zero pad at least about 3800 data points (claim 29) and a motor controller applies current to stator windings in a sequence to create a rotating field, and a time continuous signal includes a stator winding current (claim 25) and a received time continuous signal from a blood pump comprises less than about 200 sampled data points of a time continuous signal (claim 28). However, it is well known in the art to program a processor to calculate a signal to noise ratio and a signal to noise plus distortion ratio to enhance signal demodulation and message recovery or to indicate viable recovered message fidelity. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Antaki et al. to include programming a processor to calculate a signal to noise ratio and a signal to noise plus distortion ratio to enhance signal demodulation and message recovery or to indicate viable recovered message fidelity. Further, it is well known in the art to program a processor to zero pad a received time continuous signal to advantageously extend a signal or spectrum to extend its time or frequency limits for enhancing signal resolution. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Antaki et al. to include programming a processor to zero pad a received time continuous signal to advantageously extend a signal or spectrum to extend its time or frequency limits for enhancing signal resolution. Also, it is well known in the art that a motor controller applies current to stator windings in a sequence to create a

rotating field, and a time continuous signal includes a stator winding current because this is the basic function of a motor that enable it to perform efficiently in a system and allow the system in which it is used to operate effectively. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Antaki et al. to include a motor controller applies current to stator windings in a sequence to create a rotating field, and a time continuous signal includes a stator winding current because this is the basic function of a motor that enable it to perform efficiently in a system and allow the system in which it is used to operate effectively. Additionally, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include a received time continuous signal from a blood pump comprises less than about 200 sampled data points of a time continuous signal and a processor is programmed to zero pad at least about 3800 data points, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980). (See MPEP 2144.05).

13. Antaki et al. disclose the essential features of the claimed invention as described above except for an analog to digital converter (ADC) that converts a time continuous signal to a digital signal; and a sample mode selector connected to an analog to digital converter, a sample mode selector setting one of a synchronous sample mode or an asynchronous sample mode, wherein if an asynchronous sample mode is set, a sampling rate of an analog to digital converter is set by a reference clock; and if a synchronous sample mode is set, a sampling rate of an analog to digital converter is set according to a frequency of a time continuous signal (claim 23). However, one of ordinary skill in the art would have known to convert a time continuous signal to a digital signal using an ADC and a sample mode selector connected to an analog to digital converter to set one of a synchronous sample mode or an asynchronous sample mode, wherein if an asynchronous sample mode is set, a sampling rate of an analog to digital converter is set by a reference clock; and if a synchronous sample mode is set, a sampling rate of an analog to digital converter is set according to a frequency of a time continuous signal to ensure most advantageous operation of a blood pump for rendering optimum function of a heart. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Antaki et al. to include converting a time continuous signal to a digital signal using an ADC and connecting a sample mode selector to an analog to digital converter to set one of a synchronous sample mode or an asynchronous sample mode, wherein if an asynchronous sample mode is set, a sampling rate of an analog to digital converter is set by a reference clock; and if a synchronous sample mode is set, a sampling rate of an analog to digital converter is set according to a frequency of a time continuous signal to ensure most advantageous operation of a blood pump for rendering optimum function of a heart.

Applicant does not accede to the Office's characterizations of Antaki or with the application of Antaki to claims 18, 19 and 23 – 29. Further, the Office's conclusions as to what

Appl. No. 10/675,669
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may or may not have been obvious are moot in light of the above arguments and amendments. For at least the reasons discussed above, these claims are patentable over Antaki. Reconsideration and withdrawal of these rejections are respectfully requested.

OTHER SPECIFICATION AMENDMENTS

For reasons unrelated to any amendments made above in direct relation to a claim rejection, Applicant has chosen to the specification in several places to correct obvious typographical errors. No new matter has been added.

OTHER CLAIM AMENDMENTS

For reasons unrelated to any amendments made above in direct relation to a claim rejection, Applicant has chosen to make clarifying amendments to claims 1 and 15 - 28 to more particularly point and distinctly claim certain aspects of the disclosed inventions. These amendments may or may not be narrowing in scope and are not being made for patentability reasons.

COURTESY COPY OF CLAIMS

Included with this response as a courtesy is a listing of claims with out markup.

CONCLUSION

Claims 1-31 are currently pending in this application, with claims 1-14 and 30-31 being withdrawn from consideration. Prior to this Amendment, claims 15-29 stood rejected.

Appl. No. 10/675,669
Amdt. Dated 01/28/2007
Reply to Office Action of 10/27/2006

Claims 1 and 15 - 28 have been amended herein. Applicant submits that each claim presented herein is patentable. A timely notice of allowance is respectfully requested.

Applicant thanks the Examiner for his consideration and effort on this file. If there are any questions or if additional information is needed, the Examiner is invited to telephone or email the undersigned.

Respectfully submitted,

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COURTESY COPY OF CLAIMS WITHOUT MARKUP

1. (Withdrawn) A method of controlling a blood pump, comprising:
 - sampling a time continuous signal from the blood pump;
 - transforming the sampled time continuous signal to the frequency domain;
 - analyzing the sampled time continuous signal in the frequency domain;
 - controlling the blood pump in response to analysis of distortion in the sampled time continuous signal in the frequency domain; and
 - detecting excess suction in response to the analysis of the sampled time continuous signal in the frequency domain.
2. (Withdrawn) The method of claim 1, further comprising determining parametric data in response to the analysis of the sampled time continuous signal in the frequency domain.
3. (Withdrawn) The method of claim 2, wherein the parametric data include heart rate.
4. (Withdrawn) The method of claim 3, further comprising zero padding the time continuous signal.
5. (Withdrawn) The method of claim 4, wherein sampling the time continuous signal from the blood pump includes sampling less than about 200 data points of the time continuous signal.
6. (Withdrawn) The method of claim 5, further comprising zero padding at least about 3800 data points.
7. (Withdrawn) The method of claim 2, wherein the parametric data include respiratory rate.
8. (Withdrawn) The method of claim 2, wherein the parametric data include pump flow rate.
9. (Withdrawn) The method of claim 1, further comprising validating the sampled time continuous signal in response to the analysis of the sampled time continuous signal in the frequency domain.
10. (Withdrawn) The method of claim 9, wherein validating the sampled time continuous signal includes evaluating the signal to noise ratio.

11. (Withdrawn) The method of claim 9, wherein validating the sampled time continuous signal includes evaluating the signal to noise plus distortion ratio.
12. (Withdrawn) The method of claim 1, wherein the time continuous signal comprises the pump flow rate.
13. (Withdrawn) The method of claim 1, wherein the time continuous signal comprises the pump speed.
14. (Withdrawn) The method of claim 1, wherein the time continuous signal comprises the pump current.
15. (Currently amended) A blood pump control system, comprising:
 - a processor adapted to receive a time continuous signal from a blood pump; and
 - wherein the processor is programmed to transform the time continuous signal to the frequency domain, and to detect excess suction in response to distortion in the transformed time continuous signal.
16. (Canceled) The system of claim 15, wherein the processor is further programmed to determine parametric data based on the transformed time continuous signal, the processor including an output terminal for outputting the parametric data.
17. (Currently amended) The system of claim 15, wherein the processor is programmed to validate the time continuous signal based on the transformed time continuous signal.
18. (Currently amended) The system of claim 17, wherein the processor is programmed to calculate the signal to noise ratio of the transformed time continuous signal.
19. (Currently amended) The system of claim 17, wherein the processor is programmed to calculate the signal to noise plus distortion ratio of the transformed time continuous signal.
20. (Currently amended) The system of claim 15, further comprising a flow measurement device adapted to transduce the pump flow rate, and wherein the processor is adapted to receive a signal indicating the pump flow rate.
21. (Currently amended) The system of claim 15, wherein the processor is connected to the pump to receive a signal indicating the pump speed.
22. (Currently amended) The system of claim 15, wherein the processor is connected to the

pump to receive a signal indicating the pump current.

23. (Currently amended) The system of claim 15, further comprising:

- an analog to digital converter having a sampling rate and that digitizes at least a portion of the time continuous signal; and

- a sample mode selector connected to the analog to digital converter, the sample mode selector setting one of a synchronous sample mode or an asynchronous sample mode, wherein

- if the asynchronous sample mode is set, the sampling rate of the analog to digital converter is set by a reference clock; and

- if the synchronous sample mode is set, the sampling rate of the analog to digital converter is set according to the frequency of the time continuous signal.

24. (Currently amended) A blood pump system, comprising:

- a blood pump comprising a rotor and a stator, the stator including a plurality of stator windings;

- a controller operatively coupled to the pump;

- a processor operatively coupled to the controller and adapted to receive a time continuous signal from the pump; and

- wherein the processor is programmed to transform the time continuous signal to the frequency domain, and to detect excess suction in response to distortion in the transformed time continuous signal.

25. (Currently amended) The blood pump system of claim 24, wherein the controller applies current to the stator windings in a sequence to create a rotating field, and wherein the time continuous signal includes one or more stator winding current.

26. (Currently amended) The blood pump system of claim 24, further comprising a flow measurement device coupled to the processor and providing a signal representing the pump flow rate, wherein the time continuous signal includes the pump flow rate.

27. (Currently amended) The blood pump system of claim 24, wherein the processor is programmed to zero pad a digital representation of the received time continuous signal.

28. (Currently amended) The blood pump system of claim 27, wherein the digital representation of the received time continuous signal from the blood pump comprises less than about 200 data points of the time continuous signal.

29. (Original) The blood pump system of claim 28, wherein the processor is programmed to zero pad at least about 3800 data points.

30. (Withdrawn) A method of determining heart rate, comprising: sampling a time continuous signal from a blood pump at a predetermined sampling frequency for a predetermined time period to obtain a sample N; zero padding the sampled time continuous signal to achieve a sample M, where M is greater than N; transforming the zero padded time continuous signal to the frequency domain; and determining a heart rate based on the frequency domain representation.

31. (Withdrawn) The method of claim 30, wherein the frequency domain representation of the zero padded time continuous signal comprises a spectral peak at a frequency proportional to the heart rate.